



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

m3894h

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Chun H. Chan, President
Luen Hing Sprouts, Inc.
372 Broome Street
New York, NY 10013

June 28, 2000

Ref: NYK-2000-81

Dear Mr. Chan:

We inspected your bean sprout production facility located at the above address on May 31 through June 2, 2000. We found that you have failed to adopt effective preventive controls to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and to assure that sprouts are not adulterated under the food safety provisions of the Federal Food, Drug, and Cosmetic Act ("the Act"). Your failure to adopt effective controls causes your sprouts to be in violation of section 402(a)(4) of the Act.

Specifically, your sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they have been prepared, packed or held under unsanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your sprouting facility. Further, during the inspection, the investigator observed flying insects in the sprout production and storage areas. The back and front doors of the facility were open and there were no screen doors at these entries. There were no effective measures taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when the corrections will be completed.

This letter may not list all the violations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act and the Good Manufacturing Practice Regulations (Title 21, *Code of Federal Regulations*, Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. You can find this Act and guidance for the bean sprout industry through links on FDA's home page at www.fda.gov. For your information, we are also enclosing copies of the following industry guidance documents: "Reducing Microbial Food Safety Hazards for Sprouted Seeds" and "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have any questions regarding any issue in this letter, please contact Mr. Goldwitz at 718/340-7000 ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman", with a stylized flourish at the end.

Brenda J. Holman
District Director

Enclosures: as stated

Luen Hing Sprouts, Inc. – Page 3

cc: HFR-NE1
cc: HFR-NE100
cc: HFR-NE140/QA file
cc: HFR-NE150
cc: HFR-NE150/R. Ferfoggia/K. Lee
cc: HFS-607/CFSAN/W. Correll *Fax by program*
cc: HFA-224
cc: HFC-210/DCMO (CFN 2433579)
cc: HFI-35/redacted copy
cc: EF (Luen Hing Sprouts, Inc., CFN 2433579)
cc: warning letter file (NYK-2000-81)
cc: BAG

DCB approval 6/26/00
FACTS 3411-0